UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

NYCOMED GmbH and WYETH Plaintiffs, v. APOTEX Inc. and APOTEX Corp. Defendants	Civil Action No.: 1:09-cv-04999 Honorable Judge Virginia M. Kendall Magistrate Judge Morton Denlow **JURY TRIAL DEMANDED** **Filed Electronically**

ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS OF APOTEX INC. AND APOTEX CORP. TO COMPLAINT FOR PATENT INFRINGEMENT

Defendants Apotex Inc. and Apotex Corp., through counsel, hereby answer the Complaint For Patent Infringement of Plaintiffs Nycomed GmbH and Wyeth ("Complaint") as follows:

1. Nycomed GmbH is a corporation incorporated and existing under the laws of Germany, having its principal place of business at Byk-Gulden-Str. 2, 78467 Konstanz, Germany.

Answer:

Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within paragraph 1 of the Complaint, and on that basis deny such averments.

2. Wyeth is a Delaware corporation with offices at Five Giralda Farms, Madison, NJ 07940.

Answer:

Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within paragraph 2 of the Complaint, and on that basis deny such averments.

3. Nycomed GmbH is at times referred to hereinafter as "Nycomed."

Answer:

The averments contained in Paragraph 3 are not factual or legal allegations and no response is required.

4. Upon information and belief, Defendant Apotex Inc. is a corporation incorporated and existing under the laws of Canada and having a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

Answer:

Defendants Apotex Inc. and Apotex Corp. admit that Apotex Inc. is a company incorporated and existing under the laws of Canada and having a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

5. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

Answer:

Defendants Apotex Inc. and Apotex Corp. admit that Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

6. Upon information and belief, Apotex Corp. is the agent, affiliate, representative and/or alter ego of, and/or acts in concert with, Apotex Inc. for purposes of marketing, distributing, and/or selling generic pharmaceutical products within the United States, including this district.

Answer:

Defendants Apotex Inc. and Apotex Corp. deny the averments in Paragraph 6 of the Complaint.

7. Apotex Inc. and Apotex Corp. are at times referred to hereinafter as "Apotex."

Answer:

The averments contained in Paragraph 7 are not factual or legal allegations and no response is required.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America, and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a).

Answer:

Paragraph 8 of the Complaint alleges Plaintiffs' statutory basis for asserting jurisdiction in this Action which does not require an answer. Apotex Inc. and Apotex Corp. admit that this Court has subject matter jurisdiction over the subject matter of this action.

9. Upon Information and belief, Apotex Inc. develops and manufactures generic drugs for sale and use in the United States and does business throughout the United States, including in this district.

Answer:

Defendants Apotex Inc. and Apotex Corp. admit Apotex Inc. develops and manufactures generic drugs some of which are sold and used in the United States. Defendants Apotex Corp. and Apotex Inc. deny the remaining averments of Paragraph 9 of the Complaint.

10. Upon information and belief, Apotex Corp. is the United States marketing and sales affiliate for Apotex Inc. and does business throughout the United States, including in this district.

Answer:

Defendants Apotex Inc. and Apotex Corp. deny the averments of Paragraph 10 of the Complaint.

11. Apotex, Inc. has designated Steven E. Feldman of Husch Blackwell Sanders Welsh & Katz, 120 South Riverside Plaza, 22nd Floor, Chicago, Illinois 60606, as its agent authorized to accept service of process in this action, and has thereby consented to personal jurisdiction in this district.

Answer:

Defendants Apotex Inc. and Apotex Corp. admit that Steven E. Feldman of Husch Blackwell Sanders Welsh & Katz, 120 South Riverside Plaza, 22nd Floor, Chicago, Illinois 60606, is designated as an authorized agent for service of process solely with respect to Apotex Inc.'s submission of an Abbreviated New Drug Application ("ANDA") for Pantoprazole Sodium Tablets 20 mg and 40 mg. Defendants Apotex Inc. and Apotex Corp. deny the remaining averments in Paragraph 11 of the Complaint. Further answering, Defendants Apotex Inc. and Apotex Corp. do not contest personal jurisdiction in this District for the purpose of this Action.

12. Upon information and belief, Apotex has maintained continuous and systematic contacts with the State of Illinois and this district.

Answer:

For purposes of this Action, Defendants Apotex Inc. and Apotex Corp. do not contest the Court's jurisdiction over it, but denies the alleged basis for personal jurisdiction.

13. Upon information and belief, Apotex has previously submitted to personal jurisdiction in this district.

Answer:

Defendants Apotex Inc. and Apotex Corp. admit the allegations of paragraph 13 of the Complaint.

14. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

Answer:

Paragraph 14 of the Complaint alleges Plaintiffs statutory basis for asserting venue in this Action which does not require an answer. Defendants Apotex Inc. and Apotex Corp., further state that, for purposes of this Action, they do not contest venue in this District.

BACKGROUND FOR CLAIM FOR RELIEF UNDER 35 U.S.C. § 271(e)

15. Wyeth Pharmaceuticals Inc., a wholly-owned subsidiary of Wyeth, is the holder of New Drug Application ("NDA") No. 20-987, by which the United States Food & Drug Administration ("USFDA") granted approval for pantoprazole sodium 20 mg and 40 mg delayed-release tablets, which are marketed and sold by Plaintiffs in the United States under the trade name PROTONIX®.

ANSWER:

Defendants Apotex Inc. and Apotex Corp. admit that Wyeth Pharmaceuticals Inc. is listed as Applicant for NDA No. 20-987 for Protonix® of which the active ingredient is pantoprazole. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within Paragraph 15 of the Complaint, and on that basis deny such averments.

16. Nycomed is the owner of United States Patent No. 4,758,579 ("the '579 patent"), which was duly and legally issued on July 19, 1988, and discloses and claims certain compounds useful for inhibiting gastric acid secretion, including pantoprazole sodium, the active ingredient of PROTONIX®.

Answer:

Defendants Apotex Inc. and Apotex Corp. admit only so much of paragraph 16 of the Complaint as alleges that U.S. Patent No. 4,758,579, entitled "Fluoroalkoxy Substituted Benzimidrazoles Useful As Gastric Acid Secretion Inhibitors," was issued by the U.S. Patent and

Trademark Office ("PTO") on July 19, 1988; that, according to the PTO's electronic assignment database, Plaintiff Nycomed GmbH is now the assignee of the '579 patent; and that, according to the electronic version of the FDA Orange Book, pantoprazole sodium is the listed active ingredient of PROTONIX®. Defendant Apotex Inc. and Apotex Corp. deny the remaining allegations of paragraph 16 of the Complaint.

17. Wyeth is the exclusive licensee of the '579 patent in the United States.

Answer:

Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 17 of the Complaint and, on that basis deny such averments.

18. A copy of the '579 patent is attached as Exhibit A.

Answer:

The averments contained in Paragraph 18 are not factual or legal allegations and no response is required.

19. The expiration date of the '579 patent is July 19, 2010.

Answer:

Defendants Apotex Inc. and Apotex Corp. admit only that, according to the records of the PTO, the term of the '579 patent appears to have been extended an additional 5 years to July 19, 2010 pursuant to 35 U.S.C. § 156. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments contained within Paragraph 19 of the Complaint, and on that basis deny such averments

20. Plaintiffs have been awarded a period of pediatric exclusivity that extends their exclusive rights under the ’579 patent until January 19, 2011.

Answer:

Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments of Paragraph 20, and on that basis deny such averments.

21. Upon information and belief, Apotex filed in the USFDA an Abbreviated New Drug Application (“ANDA”), No. 90-807, including a certification with respect to the ’579 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of pantoprazole sodium 20 mg and 40 mg delayed-release tablets, prior to expiration of the ’579 patent.

Answer:

Defendants Apotex Inc. and Apotex Corp. admit only so much of Paragraph 21 of the Complaint as alleges that Apotex Inc. filed ANDA 90-807, including a certification with respect to the ’579 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of pantoprazole sodium tablets 20 mg and 40 mg, prior to expiration of the ’579 patent. Defendants Apotex Inc. and Apotex Corp. deny the remaining averments of Paragraph 21 of the Complaint.

22. Upon information and belief, pantoprazole sodium is the active ingredient of the products for which Apotex is seeking regulatory approval in ANDA No. 90-807.

Answer:

Defendants Apotex Inc. and Apotex Corp. admit pantoprazole sodium is the active ingredient of the product that is the subject of ANDA No. 90-807.

23. Upon information and belief, the pantoprazole sodium drug substance and the pantoprazole sodium delayed-release tablets that are the subject of ANDA No. 90-807 will be manufactured by Apotex.

Answer:

Defendants Apotex Inc. and Apotex Corp. admit only so much of Paragraph 23 of the Complaint that alleges that Apotex Inc. filed ANDA No. 90-807 seeking FDA approval to, in *inter alia*, commercially manufacture pantoprazole sodium tablets 20 mg and 40 mg. Defendants Apotex Inc. and Apotex Corp. deny the remaining averments of Paragraph 23 of the Complaint.

24. Upon information and belief, Apotex intends to --- directly or indirectly --- market, sell, offer for sale, and distribute the products that are the subject of ANDA No. 90-807, including within this district, upon regulatory approval.

Answer:

Defendants Apotex Inc. and Apotex Corp. admit only so much of Paragraph 24 of the Complaint that alleges, with respect to Apotex Inc.'s filing of ANDA No. 90-807, that it is seeking regulatory approval from the FDA to market, sell, offer for sale, and distribute pantoprazole sodium tablets 20 mg and 40 mg in the United States. Defendants Apotex Inc. and Apotex Corp. deny the remaining averments of Paragraph 24 of the Complaint.

25. By letter dated July 3, 2009, Apotex sent a notice to Nycomed and Wyeth in which Apotex represented that it has filed an ANDA for pantoprazole sodium delayed-release tablets, including the certification with respect to the '579 patent, and that it sought approval of its ANDA prior to expiration of that patent.

Answer:

Defendants Apotex Inc. and Apotex Corp. admit only so much of Paragraph 25 of the Complaint as alleges that it sent a letter, dated July 3, 2009, to Nycomed GmbH, Wyeth

Pharmaceuticals Inc. and Altana Pharma AG providing notice, including a Paragraph IV certification with respect to the '579 patent, that it had filed an ANDA for pantoprazole sodium tablets 20 mg and 40 mg and seeking FDA approval prior to expiration of the '579 patent, including Apotex's Paragraph IV Certification to the FDA with respect to the '579 patent. Defendants Apotex Inc. and Apotex Corp. deny the remaining averments of Paragraph 25 of the Complaint.

26. Nycomed received notice of the Apotex certification no earlier than July 7, 2009.

Answer:

Defendants Apotex Inc. and Apotex Corp., are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within Paragraph 26 of the Complaint, and on that basis deny such averments.

27. Wyeth received notice of the Apotex certification no earlier than July 7, 2009.

Answer:

Defendants Apotex Inc. and Apotex Corp., are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within Paragraph 27 of the Complaint, and on that basis deny such averments.

CLAIMS FOR RELIEF UNDER 35 U.S.C. § 271(E)

28. Because Apotex seeks approval of ANDA No. 90-807 to engage in the commercial manufacture, use, importation, sale and/or offer for sale of a drug claimed in the '579 patent before its expiration, Apotex has infringed the '579 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

Answer:

Defendants Apotex Inc. and Apotex Corp. deny the averments of Paragraph 28 of the Complaint.

29. Apotex actively and knowingly submitted, caused to be submitted, assisted with, participated in, contributed to and/or directed the submission of ANDA No. 90-807 and the § 505(j)(2)(A)(vii)(IV) certification to the FDA.

Answer:

Defendants Apotex Inc. and Apotex Corp. admit only so much of Paragraph 29 of the Complaint as alleges that Apotex Inc. submitted ANDA No. 90-807, containing a § 505(j)(2)(A)(vii)(IV) certification to the FDA. Defendants Apotex Inc. and Apotex Corp..deny the remaining averments of Paragraph 29 of the Complaint.

30. Apotex's active and knowing participation in, contribution to, aiding, abetting and/or inducement of the submission of the FDA of ANDA No. 90-807 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '579 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Defendants Apotex Inc. and Apotex Corp. deny the averments of Paragraph 30 of the Complaint.

31. Nycomed and Wyeth are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 90-807 be a date that is not earlier than the expiration date of the '579 patent and all exclusivities that have been granted, including pediatric exclusivity, or any later expiration of exclusivity for the '579 patent to which Nycomed and/or Wyeth is or becomes entitled.

Answer:

Paragraph 31 of the Complaint sets forth Plaintiffs legal conclusions as to the relief it is entitled to receive under 35 U.S.C. § 271(3)(4) for which an answer is not required. However, to the extent that Paragraph 31 may be deemed to require an answer, Defendants Apotex Inc. and Apotex Corp. deny the averments in Paragraph 31 of the Complaint.

32. Upon information and belief, Apotex was aware of the existence of the '579 patent and was aware that the filing of its ANDA and certification with respect to the '579 patent constituted an act of infringement on that patent.

Answer:

Defendants Apotex Inc. and Apotex Corp. admit only so much of Paragraph 32 as generally alleges that they are aware of the '579 patent . Apotex denies the remaining averments of this Paragraph.

GENERAL DENIAL

Any allegations in Plaintiffs' Complaint not expressly admitted by Defendants are hereby denied. Having answered Plaintiffs' Complaint, Defendants deny that Plaintiffs are entitled to the relief requested in Plaintiffs' Prayer for Relief or any relief whatsoever.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not otherwise admitted, Defendants assert the following defenses to the Complaint. Defendants reserve the right, following a reasonable opportunity for further investigation, to raise additional defenses and counterclaims.

FIRST AFFIRMATIVE DEFENSE: FAILURE TO STATE A CLAIM

Plaintiffs have failed to state a claim on which relief can be granted.

SECOND AFFIRMATIVE DEFENSE: INVALIDITY

The claims of the '579 patent are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD AFFIRMATIVE DEFENSE: NON- INFRINGEMENT

The manufacture, use, importation, offer for sale, or sale of pantoprazole sodium tablets 20 mg and 40 mg that are the subject of Apotex Inc.'s ANDA No. 90-807 has not infringed, does not infringe, and would not, if marketed, infringe one or more of the claims of the '579 patent.

COUNTERCLAIMS

Apotex Inc. and Apotex Corp. (collectively "counterplaintiffs") for their Counterclaims against Nycomed GmbH ("Nycomed") and Wyeth (collectively "counterdefendants"), allege as follows:

PARTIES AND JURISDICTION

1. Plaintiff Nycomed GmbH ("Nycomed") has alleged that it is a corporation incorporated and existing under the laws of Germany, having its principal place of business at Byk-Gulden-Str. 2, 78467 Konstanz, Germany. *See* Complaint (DI 1), ¶1.

2. Plaintiff Wyeth has alleged that it is a Delaware corporation with offices at Five Giralda Farms, Madison, NJ 07940. *See* Complaint (DI 1), ¶2.

3. Apotex Inc. is a Canadian corporation having its principal place of business at 150 Signet Drive, Weston, Ontario M9L 1T9, Canada.

4. Apotex Corp. is a Delaware corporation having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

5. Wyeth has alleged that its wholly-owned subsidiary, Wyeth Pharmaceuticals Inc., is the holder of NDA No. 20-987 by which the FDA has granted approval for pantoprazole sodium 20 mg and 40 mg delayed-release tablets to be marketed and sold in the United States under the trade name PROTONIX®. *See* Complaint (DI 1), ¶15.

6. Nycomed has alleged that it is the owner of the '579 patent which discloses and claims pantoprazole sodium that is the active ingredient of PROTONIX®. *See* Complaint (DI 1), ¶16.

Jurisdiction and Venue

7. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.,* the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.,* as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §355) (hereinafter "Hatch-Waxman Amendments"), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (hereinafter "MMA").

8. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§1331 and 1338(a).

9. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c), and 1400 (b).

Patent-in-Suit

10. On or about July 19, 1988, the United State Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,758,579 ("the '579 patent"), entitled "FLUOROALKOXY SUBSTITUTED BENZIMIDAZOLES USEFUL AS GASTRIC ACID SECRETION INHIBITORS" to Bernhard Kohl, Ernst Sturm, and Georg Rainer.

11. Nycomed purports to own the '579 patent. *See* Complaint (DI 1), ¶16.

12. Wyeth purports to be the exclusive licensee of the '579 patent in the United States. *See* Complaint (DI 1), ¶17.

13. Plaintiffs purport that Wyeth Pharmaceuticals, Inc. is a wholly-owned subsidiary of Wyeth. *See* Complaint (DI 1), ¶15.

14. Wyeth Pharmaceuticals, Inc. is identified as the owner of New Drug Application No. 20-987 for Protonix® brand pantoprazole sodium tablets 20mg and 40 mg. The ’579 patent is listed in the Orange Book for Protonix®.

15. Wyeth and Nycomend have attempted to enforce the ’579 patent against one of more abbreviated new drug application (“ANDA”) filers seeking FDA approval for pantoprazole sodium tablets 20 mg. and 40 mg.

16. Apotex has submitted ANDA No. 90-807 to the FDA. Apotex, Inc.’s ANDA seeks FDA approval for the commercial manufacture, use, importation, offer for sale, and sale of generic pantoprazole sodium tablets 20 mg. and 40mg.

17. Pursuant to 21 U.S.C. § 355(j)(2)(B)(i) and (ii) and 21 C.F.R. § 314.95, Apotex has certified to Wyeth and Nycomed that the ’579 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, offer for sale, or sale of the new drug for which ANDA 90-807 is submitted.

18. On or about July 3, 2009, Apotex, Inc. served Wyeth and Nycomed with a Notice letter informing Wyeth and Nycomed of its ANDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of its pantoprazole sodium tablets 20 mg and 40mg before the expiration of the ’579 patent, and that its ANDA included a Paragraph IV Certification.

19. On or about August 14, 2009, Wyeth and Nycomed sued Apotex Inc. and Apotex Corp. in this District alleging infringement of the ’579 patent under 35 U.S.C. § 271 (e)(2)(A).

20. As a result of Wyeth’s actions in listing the ’579 patent in the Orange Book and in suing counterplaintiffs for alleged infringement of the ’579 patent, counterplaintiffs are presently prevented from selling pantoprazole sodium tablets 20 mg and 40 mg and are being injured as a

result. Counterplaintiffs seek patent certainty with respect to the '579 patent and certainty regarding the legal rights relating to Apotex Inc.'s ANDA through a judicial declaration that the '579 patent is not infringed by the pantoprazole identified in Apotex Inc.'s ANDA, and/or that the patent is invalid.

21. A real, actual, and justiciable controversary exists between counterplaintiffs and Wyeth and Nycomed regarding the invalidity and non-infringement of the '579 patent and counterplaintiffs' non-infringement thereof, constituting a case of actual controversary within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

COUNT I
(Declaration of Non-Infringement of the '579 Patent)

22. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-21.

23. The manufacture, use, sale, offer for sale, or importation into the United States of the pantoprazole sodium tablets 20 mg and 40 mg that are the subject of Apotex Inc.'s ANDA No. 90-807 have not infringed, do not infringe, and could not, if marketed, infringe any valid or enforceable claim of the '579 patent. The claims of the '579 patent are invalid and therefore not infringed.

24. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale, or importation in the United States of the pantoprazole sodium tablets 20 mg and 40 mg that are the subject of Apotex Inc.'s ANDA No. 90-807 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '579 patent.

COUNT II
(Declaration of Invalidity of the ’579 Patent)

25. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-24.

26. The claims of the ’579 patent are invalid pursuant to 35 U.S.C. § 102 and/or 103 in view of the prior art, including but not limited to, U.S. Patent No. 4,045,563 (Berntsson I), U.S. Patent No. 4,045,564 (Berntsson II), U.S. Patent No. 4,255,431 (Junggren I), U.S. Patent No. 4,435,406 (Krasso), U.S. Patent No. 4,472,409 (Senn-Bilfinger), U.S. Patent No. 4,555,518 (Rainer I), U.S. Patent No. 4,560,693 (Rainer II), U.S. Patent No. 4,686,230 (Rainer III), Sachs, “Pump Blockers and Ulcer Disease,” New Eng. J. Med. (March 22, 1984) 310(12):785-786, HANDBOOK OF BIOCHEMISTRY, H.A. Sober Ed., The Chemical Rubber Co., Cleveland, p. J216 (1970), and Bryson, “The Ionization Constants of 3-Substituted Pyridines, 3-Substituted Quinolines and 4-Substituted Isoquinolines,” J. Am. Chem. Soc., 82:4871-4876 (1960), Berge, S. M., Bighley, L. D., Monkhouse, D. C. (1977) *J. Pharm. Sci.* **66**:1-19, either individually, in combination with the knowledge of the person having ordinary skill in the art, or in combination with each other.

27. Proton pump inhibitors with structures similar to, if not identical to, those claimed in the ’579 patent, including pantoprazole, already were well known in the prior art. The differences between the subject matter claimed in the ’579 patent and the prior art are such that, at the time of the invention, the subject matter as a whole claimed in the ’579 patent would have been obvious to a person having ordinary skill in the art in view of the prior art. For example, compound 12 of the Rainer I patent is identical to pantoprazole except that it has a methyl rather than a methoxy group at the 3-position on the pyridine ring. The prior art taught to substitute a methoxy group for the methyl group at the 3-position to improve in vivo stability of compounds

of this type, which would have provided motivation to a person of ordinary skill in the art to modify compound 12 to make pantorprazole with a reasonable expectation of success. The properties of pantoprazole would not have been unexpected to a person of ordinary skill in the art.

28. Counterplaintiffs are entitled to a declaration that the claims of the ’579 patent are invalid.

DEMAND FOR JUDGMENT AND PRAYER FOR RELIEF

WHEREFORE, Defendants Apotex Inc. and Apotex Corp., respectfully request that this Court enter a Judgment and Order in its favor and against Plaintiffs Wyeth and Nycomed as follows:

a. Declaring that the claims of the ‘579 patent are invalid.

b. Declaring that the manufacture, use, sale, offer for sale, or importation into the United States of the pantoprazole sodium tablets 20 mg and 40 mg that is subject to Apotex Inc.’s ANDA 90-807 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the ‘579 patent.

c. Awarding to Apotex Inc. and Apotex. Corp. its costs, expenses, and reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

d. Declaring that the Food & Drug Administration may approve Apotex’s Abbreviated New Drug Application (No. 90-807) concerning pantoprazole sodium tablets 20 mg and 40 mg whenever that application is otherwise in condition for approval, without awaiting any further order, judgment or decree of this court; that the judgment entered in this case is a judgment reflecting a decision that the patent in suit is invalid pursuant to 21 U.S.C. §355(j)(5)(B)(iii)(I)(aa); and that the thirty-month period referred to in 21 U.S.C.

§ 355(j)(5)(B)(iii) and any other marketing exclusivity periods to which Plaintiffs might otherwise be entitled (including any pediatric exclusivity) are shortened to expire upon the date of entry of judgment in this case.

e. Awarding such other relief that the Court deems just and proper under the circumstances.

JURY DEMAND

Defendants Apotex Inc. and Apotex Corp. demand a trial by jury with respect to all issues that are triable to a jury as a matter of right.

Dated: November 9, 2009

Respectfully submitted,

/s/ Sherry L. Rollo

Steven E. Feldman
Hartwell P. Morse, III
Sherry L. Rollo
HUSCH BLACKWELL SANDERS LLP WELSH & KATZ
120 South Riverside Plaza, Suite 2200
Chicago, Illinois 60606
Phone: (312) 655-1500
Fax:(312) 655-1501

Attorneys for Defendants, Apotex Inc.. and Apotex Corp.

CERTIFICATE OF SERVICE

I, the undersigned attorney for Defendants Apotex Inc. and Apotex Corp., hereby certify that a true and correct copy of the foregoing ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS OF APOTEX INC. AND APOTEX CORP. TO COMPLAINT FOR PATENT INFRINGEMENT was filed by the Court's Electronic Case Filing (ECF) and served as follows on counsel for Plaintiffs on the 9th day of November, 2009:

Via Electronic Filing (ECF) and Email:

James B. Coughlan
PAUL, HASTINGS, JANOFSKY & WALKER LLP
191 North Wacker Drive, 30th Floor
Chicago, IL 60606
jamescoughlan@paulhastings.com

Via Email

Joseph M. O'Malley, Jr.
Bruce M. Wexler
Eric W. Dittman
Isaac S. Ashkenazi
PAUL, HASTINGS, JANOFSKY & WALKER LLP
75 East 55th Street
New York, New York 10022
josephomalley@paulhastings.com
brucewexler@paulhastings.com
ericdittman@paulhastings.com
issacashkenazi@paulhastings.com

William F. Lee
WILMER CUTLER PICKERING HALE AND DORR LLP
60 State Street
Boston, Massachusetts 02109
William.lee@wilmerhale.com

William G. McElwain
Amy Kreiger Wigmore
WILMER CUTLER PICKERING HALE AND DORR LLP
1875 Pennsylvania Avenue, N.W.
Washington, D.C. 20006
William.mcelwain@wilmerhale.com
Amy.kreiger@wilmerhale.com

Attorneys for Plaintiffs
Nycomed GmbH and Wyeth

Dated: November 9, 2009

/s/ Sherry L. Rollo
Sherry L. Rollo

Attorney for Defendants, Apotex Inc.. and Apotex Corp.